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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/664,462 | 09/18/2000 | Paul R. Mathewson | 0313.MATH.CN1 | 4305 |

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EXAMINER

LEWIS, KIM M

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 09/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

AJ

| | | | |
|------------------------------|--------------------------|--------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/664,462 | MATHEWSON, PAUL R. | |
| | Examiner Kim M. Lewis | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 26 September 2000.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,2 and 4-20 is/are rejected.

7) Claim(s) 3 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 18 September 2000 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <i>Detailed Action</i> . |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement papers filed 9/26/00 have been received and made of record in the application file wrapper. Note acknowledged PTO-1449 form.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Applicant is advised to update the reference in the specification.

Drawings

The drawings are objected to because of the following:

Fig. 14 is a cross-sectional view, however, no cross-hatchings are shown. See MPEP 608.02 (h)(3). Reference character "206" is missing from Fig. 2 (see page 17, line 17 of the specification). Reference characters "76", "76", "118", "121" and "123" are missing from the specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid

abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 11 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claim 4, it is unclear as to what the proximal and distal end of the bracing members are attached. The examiner will assume the ends are attached to the undersleeve.

As regards claim 11, the phrase "a second stabilizing strap" is indefinite in that the applicant has not claimed a first stabilizing strap in this branch of claims. Since it is applicant's first introduction of a strap in this branch of claims, the applicant should refer to this strap as --a first stabilizing strap--.

As regards claim 17, the recitation "a closable opening extending from said distal edge" is indefinite in that the examiner is unclear as to whether this closable opening is the same as the closable opening recited in claim 13. As such, the examiner is not able to determine the metes and bounds. Prior art will not be applied to this claim until clarification is given.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,383,845 ("Nebolon"). As regards claim 1, Nebolon discloses a brace capable of providing active resistance to axial rotation and translation in a joint. The brace comprises at least one circumferentially spiraling, length-adjustable bracing member (14, 16) (col. 4, lines 3-32) having a proximal end for positioning on one side of a joint and a distal end for positioning on the other side of a joint along a longitudinal axis formed through the joint and a circumferentially spiraling distance extending between the proximal end and the distal end defining a circumference oriented about the joint from said proximal end to said distal end. It is inherent that active resistance to axial rotation and translation of the joint is provided by a change in the circumference,

which is responsive to a change in the position of the proximal end relative to the distal end.

As regards claim 2, the bracing member is attached to a support (hinged shell 12). See Figs, 2, 3 and 5.

Claims 1, 2, 4, 5, 18 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No 6,063,048 ("Bodenschatz et al.").

As regards claims 1, 18 and 19, Bodenschatz et al. disclose an elastic joint support (brace), which reads on the instant invention. More specifically, Bodenschatz et al. disclose a bracing member support (sleeve/undersleeve 16) comprising a first bracing member (15) and a second bracing member (17), each of which is placed on opposite sides of a joint and spaced from one another in a longitudinal direction.

Bodenschatz et al. further disclose an elastic circumferentially spiraling bracing member (30) having a first end for attachment to said first bracing member and a second end for attachment to said second bracing member. The spiraling bracing member defines a circumferentially spiraling distance between its first and second ends. Bodenschatz et al. also discloses that the spiraling bracing member is stretchable in the longitudinal direction, thereby being length-adjustable, and that the spiraling bracing member has a securing structure (stitching) on both the first and second ends. The applicant should note that the support of Bodenschatz et al. is **capable** of providing active

resistance to axial rotation and translation in a joint, and that the securement structure is **capable** of maximizing lateral vector forces acting on both the first and second ends.

As regards claim 2, the ends of the spiraling bracing member are attached to the bracing member support.

As regards claim 4, the bracing member support is a sleeve having a proximal edge and a distal edge. The first end of the spiraling bracing member is attached to the proximal edge and second end of the spiraling bracing member is attached to the distal edge.

As regards claim 5, note the rejection of claims 1 and 1 above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6, 9 and 12 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bodenschatz et al. As regards claims 6 and 9, Bodenschatz et al. disclose that the sleeve is constructed from an elastic textile material (col. 3, lines 25-30). Bodenschatz et al. further disclose that first and second bracing members (bottom rim portions 15, 17)/proximal and distal portions are constructed from elastic material of sufficient elasticity to ensure that the brace remains in place during vigorous flexing and exercise of the joint (col. 3, lines 41-46). From this disclosure, one may infer that the coefficient of elasticity of the first and second bracing members is less than the coefficient of elasticity of the sleeve itself. Assuming arguendo that applicant contends that coefficient of elasticity of the first and second bracing members is not less than the coefficient of elasticity of the sleeve, the examiner contends that one having ordinary skill in the art would have been motivated by the disclosure to construct the first and second bracing members of Bodenschatz et al. from a material having a coefficient of elasticity less than that of the elastic sleeve in order to maintain the sleeve in place on the user's joint.

As regards claim 12, as can be seen from Fig. 1 of Bodenschatz et al., one of the proximal or distal portions of the sleeve is positioned and configured to serve as a bracing member support for attachment of the bracing member.

Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodenschatz et al. in view of U.S. Patent No. 5,412,957 ("Bradberry et al."). As regards claims 7 and 10, Bodenschatz et al. fail to teach the proximal and distal portions

partially encircle the sleeve to provide and expansion gap comprising material having a greater coefficient of elasticity than the coefficient of elasticity of the proximal portion. However, Bradberry et al. teach it is conventional in the art to provide sleeves with an elastic proximal portion which partially encircles the sleeve to thereby provide an expansion gap comprising material having greater coefficient of elasticity than the coefficient of elasticity of the proximal portion so as not to constrict blood flow.

In view of Bradberry et al., it would have been obvious to one having ordinary skill in the art to modify the proximal portion of the sleeve of Bodenschatz et al. to include a partially encircling elastic proximal portion to thereby provide an expansion gap comprising material having greater coefficient of elasticity than the coefficient of elasticity of the proximal portion so as not to constrict blood flow.

It would have been further obvious to one having ordinary skill in the art to duplicate the modification at the distal portion of the sleeve for the same purpose.

Claims 8 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodenschatz et al. in view of U.S. Patent No. 5,507,722 ("Richardson"). As regards claim 8, Bodenschatz et al. fail to teach a first stabilizing strap positioned in alignment with the proximal portion.

Richardson teaches it is conventional in the art to provide a stabilizing strap positioned in alignment with a proximal portion that encircles a portion of the proximal portion in order to maintain the sleeve on the user.

In view of Richardson, one having ordinary skill in the art would have been motivated to provide the sleeve of Bodenschatz et al. with a stabilizing strap positioned in alignment with the proximal portion in order to better secure (reinforce) the sleeve on the user.

As regards claim 13, Bodenschatz et al. fail to teach a closable opening. However, Richardson teaches a sleeve having a closable opening for the purpose of varying the circumference of the sleeve in order to fit various users.

In view of Richardson, one having ordinary skill in the art would have been motivated to provide the sleeve of Bodenschatz et al. with a closable opening in order to vary the circumference of the sleeve so as to fit various sized users.

As regards claim 14, Richardson discloses hook and loop fasteners to close the opening and fails to teach a zip fastener. However, the examiner contends that it would have been *prima facie* obvious to one having ordinary skill in the art to modify Richardson to include a zip fastener instead of hook and loop fasteners since both would achieve the same purpose of closing the opening in a sleeve.

As regards claims 15 and 16, note the hook and loop fasteners (18, 19).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bodenschatz et al. in view of Bradberry et al. as applied to claim 10 above, and further in view of Richardson. As regards claim 11, Bodenschatz et al. fail to teach a second stabilizing strap positioned in alignment with the distal portion.

Richardson teaches it is conventional in the art to provide a stabilizing strap positioned in alignment with a distal portion that encircles a portion of the distal portion in order to maintain the sleeve on the user.

In view of Richardson, one having ordinary skill in the art would have been motivated to provide the sleeve of Bodenschatz et al. with a stabilizing strap positioned in alignment with the distal portion that partially encircles the distal portion in order to better secure (reinforce) the sleeve on the user.

Claim 20 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nebolon. As regards claim 20, note the rejection of claim 1 in view of Nebolon above, which the provided brace. In further regard to claim 1, Nebolon discloses positioning the brace on the joint of a user and extending the bracing member from one side of a joint to the other side of the joint to define the circumferentially spiraling distance. Nebolon even further discloses selectively adjusting the length of the bracing member to thereby adjust the circumferentially spiraling distance. See Figs. 1, 6 and 7, and col. 3, line 28-col. 8, line 2.

Nebolon fails to explicitly teach a method of limiting axial rotation and translation of a joint. However, the function of actively limiting axial rotation and translation of a joint is inherent when the brace of Nebolon is placed on the joint of a user since the straps restrict movement of the joint. Assuming arguendo that the method of actively limiting axial rotation and translation is not inherent, the examiner contends that one

having ordinary skill in the art would have been motivated to use the brace of Nebolon to limit axial rotation and translation of joint since the straps restrict movement of the knee, thereby limiting axial rotation and translation of a joint.

Allowable Subject Matter

Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Mondays and Thursdays from 6:30 am to 3:00 pm.

The fax phone numbers for the organization where this application or proceeding is assigned are 703.305.3590 for regular communications and 703.305.3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.



Kim M. Lewis
Primary Examiner
Art Unit 3761

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kml
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